Clean Version of Amended Claims

1 (Original). A composition for treating or preventing an inflammatory or hyperproliferative mucocutaneous disorder, comprising a protease inhibitor and a gelling agent.

2 (Currently amended). The composition according to claim 1, wherein the protease inhibitor is an alpha 1-antitrypsin.

3 (Currently amended). The composition according to claim 2, wherein the alpha 1-antitrypsin is a natural, synthetic or recombinant alpha 1-antitrypsin.

4 (Currently amended). The composition according to claim 1, wherein the protease inhibitor is a modified peptide, biologically active fragment, substantially homologous polypeptide, oligopeptide, homodimer, heterodimer, variant, derivative, and/or an analog of alpha 1-antitrypsin.

5 (Currently amended). The composition according to claim 1, further comprising a physiological buffer at a pH from about 6 to about 9.

6 (Currently amended). The composition according to claim 5, wherein the buffer has a pH of from about 6.5 to about 7.5.

7 (Currently amended). The composition according to claim 1, wherein the gelling agent is hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid, a polyoxyethylene-polyoxypropylene block copolymer, or a combination thereof.

8 (Currently amended). The composition according to claim 1, further comprising one or more pharmaceutically active agents.

9 (Currently amended). The composition according to claim 1, which is sterile.

10 (Currently amended). A pharmaceutical composition formulated for use in preventing or treating an inflammatory or hyperproliferative mucocutaneous disorder wherein

said composition comprises a protease inhibitor and a gelling agent, and a pharmaceutical carrier.

11 (Currently amended). The composition according to claim 10, wherein the inhibitor is alpha 1-antitrypsin.

12 (Currently amended). The composition according to claim 10, wherein the composition further comprises one or more of the following:

a physiological buffer at a pH from about 6 to about 9;

a gelling agent that is hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid, a polyoxyethylene-polyoxypropylene block copolymer, or a combination thereof; and/or

one or more pharmaceutically active agents.

13 (Cancelled).

14 (Cancelled).

15 (Cancelled).

16 (Original). A method of making a protease inhibitor gel composition, comprising:

(a) mixing a powdered gelling agent with an aqueous solution to form a gel;

(b) adjusting the pH of the gel to a pH of from about 5.5 to about 9.0;

(c) sterilizing the gel; and

(d) combining a protease inhibitor with the gel to form the protease inhibitor gel.

17 (Currently amended). The method according to claim 16, wherein the aqueous solution is a physiological buffer.

18 (Currently amended). The method according to claim 16, further comprising adjusting the pH of the protease inhibitor gel from about 5.5 to about 9.0.

19 (Currently amended). The method according to claim 16, wherein the protease inhibitor is an alpha 1-antitrypsin.

20 (Currently amended). The method according to claim 16, wherein the gelling agent is hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid, polyoxyethylene-polyoxypropylene block copolymer, or a combination thereof.

21 (Currently amended). The method according to claim 16, wherein the sterilizing comprises irradiation.

22 (Currently amended). The method according to claim 16, further comprising lyophilizing the protease inhibitor gel.

23 (Currently amended). A method for the treatment or prevention of an inflammatory or hyperproliferative mucocutaneous disorder, wherein said method comprises administering to a subject in need thereof an effective amount of a composition comprising a protease inhibitor and a gelling agent.

24 (Currently amended). The method according to claim 23, wherein the protease inhibitor is an alpha-1 antitrypsin.

25 (Currently amended). The method according to claim 23, wherein the composition further comprises a physiological buffer at a pH from about 6 to about 9.

26 (Currently amended). The method according to claim 25, wherein the buffer has a pH of from about 6.5 to about 7.5.

27 (Currently amended). The method according to claim 23, wherein the gelling agent is hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid, polyoxyethylene-polyoxypropylene block copolymer, or a combination thereof.

28 (Currently amended). The method according to claim 24, wherein the alpha 1-antitrypsin is a natural, synthetic or recombinant alpha 1-antitrypsin.

29 (Currently amended). The method according to claim 23, wherein the composition further comprises one or more pharmaceutically active agents.

30 (Currently amended). The method according to claim 23, wherein the disorder is a dermatological disorder, disorder of the ear, ocular disorder, disorder of the gastrointestinal tract, or disorder of the urinary tract.

31 (Currently amended). The method according to claim 23, wherein the disorder is a dermatological disorder selected from the group consisting of atopic dermatitis; skin photodamage; extrinsic skin aging; skin irritation; chronic, burn and ulcer wounds; acne; psoriasis; lichen (particularly lichen planus); basal or squamous cell carcinoma (Bowen's disease); Kaposi's sarcoma; keratosis, such as actinic or seborrheic keratosis; and disorders of keratinization, such as ichthyosis (particularly lamellar ichthyosis) and keratoderma.

32 (Currently amended). The method according to claim 23, wherein the disorder is otitis, conjunctivitis, colitis or intestinal cystitis.

33 (Currently amended). The method according to claim 23, wherein the subject is a mammal.